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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,447	08/20/2003	Ricky W. Purcell	18189 (27839-2513)	7982

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EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1611

NOTIFICATION DATE	DELIVERY MODE
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12/09/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USpatents@armstrongteasdale.com

Office Action Summary	Application No. 10/645,447	Applicant(s) PURCELL, RICKY W.	
	Examiner Isis A. Ghali	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 08 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-43, 46, 47 and 49-62 is/are pending in the application.
- 4a) Of the above claim(s) 32-39 and 49-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-43, 46 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/23/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicant's amendment filed 10/08/2010 and IDS filed 09/23/2010.

Claims 32-43, 46, 47, 49-62 are pending.

This application contains claims 32-39, 49-62 drawn to an invention nonelected with traverse in the reply filed on 02/07/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 40-43, 46, and 47 are included in the prosecution.

Claim Rejections - 35 USC § 103

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1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 40, 41, 43, 46, 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Westplate (US 4,592,358, of record) in view of either Kanios et al. (US 6,905,016, of record) or Sudsina et al. (US 6,004,345, of record).

Applicant Claims

Applicant's claim 40 is directed to a system for providing therapy to a portion of a body, the system comprising: a container that includes at least one compartment; a first patch held by said container, wherein said first patch applies a first therapy to the portion of the body when said first patch engages the portion of the body; a second patch held by said container, wherein said second patch applies a second therapy to the portion of the body when said second patch engages the portion of the body, the

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second therapy being different than the first therapy; and a flexible wrap held by said container, the flexible wrap being adapted to secure at least one of said first patch and said second patch to the portion of the body, wherein the first patch, the second patch and the flexible wrap are all within the same compartment in the container.

Claim 41 is directed to third patch in the container. Claim 43 requires enclosure for the patches, and claims 46 and 47 require container or board as a holder. Claim 46 recites more than one first patch in the container. Claim 47 requires releasably attachment of the patches to the holder.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Westplate teaches therapeutic device (10) to treat injured parts of the body featuring a plurality of compartments (12) enclosing packets (12) containing therapeutic substances which may be a **refrigerant, which reads on endothermic patch, a heat releasing substance, which reads on exothermic patch, and a high density material or weighed packets of high density materials, which reads on third patch**, the device may be wrapped on various body portions using strap means (16) (abstract; col.2, lines 15-19; col.4, lines 20-40; col.5, lines 25-26). The packets slide easily into compartments of the device, which reads on holder as a container (col.3, lines 1-4). Packets reads on patches claimed by applicants because applicant disclosed patch as “packs, packages, inserts, buttons, and/or any other devices that is readily applied near an injured portion of the body to apply therapy”, page 5, lines 11-12 of the

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present disclosure. The figures show holder that can read on board. The device comprises a plurality of compartments, but any number of compartments may actually be filled with cooling or heating packets or weights for any particular application. The reference teaches that cooling or heating packets are removable, i.e. releasably attached (col.3, lines 6-20). A therapeutic device may be used to cool or heat, simultaneously, two different, but spaced nearby body areas (col.3, lines 26-35). The device is wrapped around the bodily injury by strap means that encircle the therapeutic device (col.5, lines 50-53). The device is flexible, and this implies that the strap is flexible so it can be wrapped around and encircles areas of the body (col.5, lines 1, 10).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Although the device taught by Westplate may be considered to be a container having at least one compartment 12, first and second patches/packets 21, and wrap 16, all being held by one device 10, as interpreted by the board, however, Westplate does not explicitly teach the patches/packets and the flexible wrap are all within the same compartment in a container.

Kanios teaches a device for stabilizing drugs in patches and transdermal devices prior to use by providing a packaging system for transdermal patches to prevent and control degradation reaction that can result from moisture contamination and environmental factors (abstract; col.4, lines 5-14). The package is in the form of

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container or box having reusable lid and loaded with multiple patches (figure 2, col.9, lines 42-50; col.10, lines 63-64). Figure 2 shows one compartment container.

Sudsina teaches kit comprising medicinal elements and a wrap, all packaged and stored in one container to be all conveniently available for use together (figure 2, col.3, lines 54-63). Figure 2 shows one compartment container.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide therapeutic device featuring a plurality of compartments enclosing packets containing therapeutic substances which may be a refrigerant, a heat releasing, or a high density material, and a wrap as taught by Westplate, and enclose the device containing the packets and the wrap in a container as taught by Kanios. One would have been motivated to do so because Kanios teaches that multiple patches can be packaged in one container to prevent and control degradation reaction that can result from moisture contamination and environmental factors. Further one would have been motivated to enclose the device containing the packets and the wrap taught by Westplate in the container taught by Sudsina because Sudsina teaches that medicinal elements and a wrap can be all packaged and stored in one container to be conveniently available for use together. One would reasonably achieved package for multiple patches providing different therapeutic effects in one

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container wherein the patches are protected against moisture and environmental factors during storage and conveniently available for use, all together when needed.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

4. Applicant's arguments filed 10/08/2010 have been fully considered but they are not persuasive.

Applicant argues that Westplate is directed to a therapeutic device featuring a plurality of compartments enclosing a various therapeutic substance, however, Westplate does not disclose or suggest placing the packets and the therapeutic device all within the same compartment in a container. The combination of Westplate, Kanios or Sudsina fails to disclose or suggest a system comprising a first patch, a second patch and a flexible wrap all within the same compartment in a container, wherein the second patch and the first patch apply different therapies to the body, as is required in Applicant's claim 40. Instead, the combination of cited references discloses placing a patch and/or packet, with a single therapy, in a container.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208

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USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, Westplate teaches therapeutic **device (10) featuring a plurality of packets (12) containing various therapeutic substances which may be a refrigerant, which reads on endothermic patch, a heat releasing substance, which reads on exothermic patch, and a high density material or weighed packets of high density materials, which reads on third patch, the device may be wrapped on various body portions using strap means (16)**. Therefore, multiple therapeutic patches in one device is taught by Westplate. Although the device taught by Westplate may be considered to be a container having at least one compartment 12, first and second patches/packets 21 that provides different therapies, and wrap 16, all being held by one device 10, as interpreted by the board, however, Westplate does not explicitly teach the patches/packets and the flexible wrap are all within the same compartment in a container. Single container is taught by both references Kanios and Sudsina. Therefore, multiple therapies from different patches is taught by Westplate, and inclusion of multiple patches in one container is taught by Kanios and Sudsina, whether the patches having the same or different therapies. In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of

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ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972).

Applicant argues that Westplate already provides for a means of protecting the packets disclosed therein and the packets are made up of a "double layer of durable, flexible, liquid impervious material." As such, why would one having ordinary skill in the art look to Kanios or Sudsina in order to have more protection from moisture contamination and environmental factors? Sudsina does not disclose or recognize the importance of having different therapies and a flexible wrap stored together within the same compartment of a container. There is no articulated reason to combine the Westplate and Kanios or Sudsina references in order to arrive at Applicant's claim 40.

In response to this argument, it is argued that multiple therapies are taught by Westplate, and further Westplate teaches inclusion of the multiple therapeutic patches in one wrap. Kanios and Sudsina teaches container containing multiple patches and possibly wrap for convenience to the user. It would have been obvious to one having ordinary skill in the art at the time of the invention to provide therapeutic device featuring a plurality of compartments enclosing packets containing therapeutic substances which may be a refrigerant, a heat releasing, or a high density material, and a wrap as taught by Westplate, and enclose the device containing the packets and the wrap in a

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container as taught by Kanios. One would have been motivated to do so because Kanios teaches that multiple patches can be packaged in one container to prevent and control degradation reaction that can result from moisture contamination and environmental factors. Further one would have been motivated to enclose the device containing the packets and the wrap taught by Westplate in the container taught by Sudsina because Sudsina teaches that medicinal elements and a wrap can be all packaged and stored in one container to be conveniently available for use together. One would reasonably achieved package for multiple patches providing different therapeutic effects in one container wherein the patches are protected against moisture and environmental factors during storage and conveniently available for use, all together when needed. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." In addition, "To determine whether there was an apparent reason to combine

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the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ". Pp. 11-14. KSR

INTERNATIONAL CO. v. TELEFLEX INC. ET AL. (2007).

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter as a whole as defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

Applicant argues that the Office is using impermissible hindsight, using Applicant's invention as a blueprint, to arrive at such a combination of the cited references.

In response to this argument, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning.

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But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, as set forth in this office action, motivation to combine the references exists in the references themselves.

5. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Westplate in view of either Kanios et al. or Sudsina et al. as applied to claims 40, 41, 43, 46 and 47 above, and further in view of Zhang et al. (US 6,245,347, of record).

Applicant Claims

Applicant's claim 42 is directed a third patch in the device that is a topical analgesic patch.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

The combined teachings of Westplate with either Kanios or Sudsina are previously discussed above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Although Westplate desired to treat injured part of the body and teaches third type of patch in the device, however, the reference does not explicitly teach an analgesic patch as claimed by claim 42.

Zhang teaches analgesic patch that can be advantageously administered along with exothermic heating or endothermic cooling means or devices to control the release and absorption of the analgesic according to the patient's need. The cooling or heating device can be applied directly to the skin and can be fixed by tape, adhesive or the like (abstract; col.5, lines 22-26; col.7, lines 35-39; col.8, lines 27-31; col.9, lines 18-31).

**Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)**

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide device for providing therapy to part of the body comprising container containing three packets/patches to treat injured part of the body including exothermic packet, endothermic packet, and third packet to provide therapy to injured portion of the body as taught by the combination of Westplate with Kanios or Sudsina, and further add analgesic patch that advantageously accompanied with cooling or heating means as taught by Zhang. One would have been motivated to add the analgesic patch because Westplate desired to treat injured parts of the body that may need analgesia and because Zhang teaches that it is advantageously to administer the analgesic patch along with exothermic heating or endothermic cooling devices to control the release and absorption of the analgesic. One would reasonable expect

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providing therapeutic device to injured part of the body comprising container containing exothermic packet, endothermic packet, and analgesic patch, wherein the system provides relief of the discomfort of the injured area and further provides controlled delivery of analgesic drug from the analgesic patch to relieve the pain and discomfort of the patient.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

6. Applicant's arguments filed 10/08/2010 have been fully considered but they are not persuasive.

Applicant argues that Zhang fails to disclose or suggest a system wherein a first patch and a second patch that provide different therapies being held with a flexible wrap within the same compartment in a container. Neither Westplate nor Zhang disclose a container that holds a flexible wrap and a first patch and a second patch with different therapies within the same compartment. Zhang teaches away from having the dermal drug delivery system in a compartment with a heating or cooling mechanism. Zhang expressly teach that the temperature control apparatus and the dermal drug delivery system are preferably stored in separate compartments of the container. As such, why

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would one having ordinary skill in the art look to place the temperature control apparatus and the dermal drug delivery system of Zhang within the same compartment?

In response to this argument, it is argued that Zhang is relied upon for the solely teaching of analgesic patch and for teaching the combination of endothermic, exothermic and analgesic patch in one device. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The elements of the present claim 42 is taught by the combination of Westplate, Kanios or Sudsina, and further Zhang, which is device comprising three patches or packets including exothermic, endothermic and analgesic patch.

Zhang does not teach away from the present invention. Zhang is an analogous art and it is in the field of applicant's endeavor and reasonably pertinent to the particular problem with which the applicant was concerned, which is transdermal drug delivery using heating element. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). The present invention as a whole is taught by the combination of the cited prior art. "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing

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from the reference's disclosure is unlikely to be productive of the result sought by the applicant." In re Gurley, 27 F.3d 551,553 (Fed. Cir. 1994).

It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." KSR Int. Co. v. Teleflex Inc., 127 S.Ct. 1727, 1740 (2007) (quoting Sakraida v. AG Pro, Inc., 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions."

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. In re Bozek, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter as a whole as defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IG

/Isis A Ghali/
Primary Examiner, Art Unit 1611